ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
Frontier Building, 3601 C Street, Room 890/896

FINAL MINUTES OF MEETING
May 19, 2006
8:00 a.m.

Committee Members Present:
Marvin Bergeson, MD
Michael Boothe, DDS
Heidi Brainerd, MS, RPh
Amber Briggs, PharmD
Richard E. Brodsky, MD
Robert Carlson, MD
Kelly Conright, MD
Jeffrey G. Demain, MD
Traci Gale, RPh (telephonic)
Vincent Greear, RPh
Thomas K. Hunt, MD
Diane Liljegren, MD (telephonic)
Andrej Maciewjewski, MD
Ronald J. Miller, RPh
Gregory R. Polston, MD (telephonic)
Janice L. Stables, MSN, ANP
George Stransky, MD
Trish D. White, RPh (telephonic)
Alexander H. vonHafften, MD (telephonic)

Committee Members Absent:
R. Duane Hopson, MD
Ronald Keller, MD
Sherrie Richey, MD

Others Present:
David Campana, RPh
Melinda Sater, PharmD - First Health

1. Call to Order

The meeting was called to order at 8:06 a.m.

2. Roll Call

A quorum was present.

3. Public Comment – Local Public/Local Physicians

Dr. Peter Ehrnstrom: Stated he was worried about losing easy access to long-acting beta agonists/inhaled corticosteroid products. He presented reasons for keeping these products unrestricted and on the PDL for asthma treatment. Over the past year, there has been concern about poor outcomes related to use of long-acting beta agonists in asthma treatment. This has lead to an FDA black box warning, even when used in combination with inhaled corticosteroids. The use of short-acting beta agonists alone is associated with poor outcomes, so it is not surprising that long-acting beta agonists may be problematic also. Inhaled corticosteroids are the preferred treatment for persistent asthma in national and international guidelines, due to their effectiveness and safety. There are several studies that demonstrate effectiveness and safety with the combined use of long-acting beta agonists and inhaled steroids. It is possible that the recent concerns about this combination is due to the fact that the concerning studies were not well-controlled for corticosteroid use. Products such as Advair with a long-acting beta agonist and inhaled corticosteroid combined in a single delivery system attain better asthma control with less corticosteroid exposure. This leads to less use of short-acting beta agonist. These also improve compliance. These are the only controller medications that assure patients are getting the two medications simultaneously. When deciding on treatment, caregivers have to balance the risk of care with the risk of not treating. When we focus on medication side effects, we should not forget the risks of not treating the illness. The National Center for Health Statistics reports that in 2002, 12 million people experienced an asthma attack in the previous year. There were 484,000 asthma hospitalizations and 4261 people died of asthma. While treating patients with asthma daily, Dr. Ehrstrom reports that he has rarely seen side effects from medications, but several times daily he sees side effects of asthma. We need to control asthma costs, which he believes can be done by improving access and removing barriers to treatment. Combination delivery system products, such as Advair, should remain on the PDL and be unrestricted due to their ability to control asthma with a single product having a favorable risk/benefit ratio. Limiting access will lead to more asthma side effects and cost. Dr. Ehrnstrom reported that he has received remuneration from several pharmaceutical companies, including Glaxo Smith-Kline, for speaking about asthma in the public and professional arenas for 20 years. He has not received any remuneration so far in 2006.

Dr. Hunt asked if Dr. Ehrnstrom would comment on the leukotriene modifiers, which are also up for review today. Dr. Ehrnstrom stated these are a very useful adjunct, particularly in young children. Often, he believes that we need to start high and come down, so he takes the guidelines and starts on the high end to obtain control. He states that compliance is a huge problem that leads to difficulties. With the current medications available, leukotriene inhibitors are useful in that situation. They are also useful in patients with multiple allergies, both upper and lower airway, which is an increasing concern. He asked that these not be restricted either.

Dr. Hunt asked if Dr. Ehrnstrom had a preferred product, and he answered he has been using Singulair only because of ease and availability. It is also easy for children to use.

Dr. Brodsky read letters from providers. Dr. Tomera wrote in about Levaquin as the preferred antibiotic, which he believes is a reasonable choice. Dr. List supports use of Levaquin also. Dr. Farr wrote that she would like suspension and oral forms of Zithromax and Biaxin included on the PDL, even though they are both macrolides. They have different coverage and tolerability. She asked that Omnicef stay on the formulary also.

4. Re-Review of Leukotriene Inhibitors

There was no public comment on this class.

Dr. Sater presented the information on this class. There are two available products, and both are FDA approved for prophylaxis and treatment of asthma in adults. Zafirlukast is indicated for asthma in children age 5 and older and montelukast in children 12 months and older. The latter is also indicated for symptomatic relief for seasonal allergic rhinitis in adults and children 2 years and older and for perennial allergic rhinitis in adults and children 6 months of age and older. There are similar contraindications, warning and adverse drug reaction profiles. Zafirlukast has to be dosed twice daily and on an empty stomach. In Alaska, there were 849 claims in April, with Singulair having 98.6% of the market share and Accolade with 1.4%. There is 100% compliance in this class, as both agents are preferred. In previous discussions, efficacy was deemed equal. Drug interaction and dosage form availability were favorable for Singulair. Discussion about utility beyond FDA indications was also discussed. Singulair was preferentially added to the PDL. Significant changes since the last review were additional indications for perennial allergic rhinitis for Singulair. Dr. Woodard prefers Singulair in his practice and he sees a significant role for this medication.

DR. HUNT MOVED TO PREFER SINGULAIR BUT CONSIDER A CLASS EFFECT. SECONDED BY DR. MACIEJEWSKI.

Dr. Demain stated that even if Accolate was included, we should require Singulair because of age recommendations. The dosing is easier also. Dr. Liljegren stated that in general, since we do not have dual eligibles on Medicaid pharmacy, we need to think about covering pregnant women and children.

Trish White and Dr. Conright joined the meeting at this time.

MOTION CARRIED UNANIMOUSLY.

5. Re-review of Nasal Steroids

Public Comment:

Dan Manning, PharmD, Schering Plough: Testified about Nasonex spray. Nasonex is one of the most commonly prescribed drugs in the inhaled nasal steroid class. It has established efficacy and safety profile and multiple indications. Allergic rhinitis affects 20 to 40% of the population. Nasonex is scent-free and alcohol free and has indication for treatment of nasal seasonal allergic and perennial allergic rhinitis in adults and children, ages 2 and up. It is also indicated for prophylaxis of seasonal allergic rhinitis. It is approved for treatment of nasal polyps in patients age 18 or older. Studies have shown this to be very safe.

Dr. Sater gave the First Health presentation on this category. Currently there are six available products in this category. All agents are FDA-approved for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis. Beclomethasone is indicated for prevention of recurrent nasal polyps following surgical removal and mometasone is indicated for treatment of nasal polyps. All are available as sprays and triamcinolone is available in aerosol form. Contraindications, warnings, adverse effects, and drug interaction profiles are similar for all products. All agents have similar efficacy and tolerability. In April there were 586 claims and Nasonex has 76% market share, flunisolide has 13%, Flonase has 4%; Nasacort AQ has 4%, Rhinocort Aqua has 3%, and

Beconase AQ has 1%. Nasonex is the single preferred agent and there is 76% compliance in this class. In previous discussions, the committee wanted to assure one aqueous solution would be available and preferentially specified Nasonex for pediatric patients. Agents were deemed equivalent for efficacy. There have been no significant changes to this class since the last review. In speaking with Dr. Woodard, he considers the agents equivalent. He considers fluticasone and mometasone to be safer molecules and adds that the fragrance in fluticasone can be problematic for some patients.

Dr. Demain stated that Flonase has a fair amount of alcohol compared to the others. This can be irritating and cause increased nose bleeds. Dr. Demain stated that what the committee discussed last time stands the same. The mometasone is a very safe molecule and well tolerated. It does not have alcohol or fragrance. Other nasal steroids are equally tolerated and they all work about the same. The efficacy has been shown to be parallel, with the exception of mometasone being better for treatment of nasal polyps. With tolerability, age preferences and trying to move away from the fragrance and alcohol, he recommended the committee continue the same as last time.

DR. DEMAIN MOVED TO STAY WITH LAST YEAR'S RECOMMENDATION TO DECLARE EQUIVALENCY, AND TO PREFER AN AQUEOUS PRODUCT WITHOUT ALCOHOL OR FRAGRANCE.

MOTION CARRIED UNANIMOUSLY.

6. Re-review of Inhalant Steroids

Dan Manning, PharmD, Schering Plough: Testified about Asmanex. This was approved in March 2005 for once daily administration, making it the only one with this dosing specification. It is also used for maintenance treatment of asthma patients. This medication has demonstrated improvements in FEV1, PS, and nocturnal symptoms in asthma patients in double blind, placebo-controlled trials and comparative trials. It is a safe medication with low systemic bioavailability of less than 1%. It has no active metabolite. Compliance with Asmanex may be better than with other products, as it is the only one approved for once daily dosing. It lets the patient know how many doses are left on the device. He stated that it is also easy to use.

Dr. Brodsky asked if there were any studies to show compliance was better, or if it is assumed this might be because it is a once a day medication. Dr. Manning replied that this is from looking at cardiovascular studies and antibiotic studies that address medication dosing at once daily versus twice daily associated with increased compliance.

Meredith Zarling, PharmD, Glaxo Smith Kline: Testified about Advair Diskus and Flovent HFA. She presented information to support retention of Advair and Flovent to the PDL. The American Lung Association of Alaska reports that 46,000 Alaskans suffer from asthma and approximately 8% of children have asthma. Among those younger than 20 enrolled in Medicaid, asthma prevalence has doubled during the three year period of 1999-2002. There is no cure for asthma, but it is manageable. There are very clear guidelines from a medical panel on asthma management. Strong evidence shows that the preferred treatment for moderate to severe asthma for adults and children over age 5 is a combination of inhaled corticosteroid and long-acting beta agonist. The only combination product available is Advair. Inflammation and bronchoconstriction are the two main causes of asthma. Proper management addresses both. Advair Diskus is easy to use and allows the patient to have both medications in a single puff administered twice daily. The patient cannot selectively discontinue

the inhaled corticosteroid therapy if they want to enjoy the benefits of a long-acting beta agonist. Three strengths are available to allow the clinician to adjust the dose of inhaled corticosteroid. Advair is indicated for long-term asthma treatment in patients 4 years and older and it is indicated for COPD associated with chronic bronchitis. In studies, Advair was significantly better than fluticasone or salmeterol alone or montelukast in improving lung function and quality of life. Advair recently had a label change stating that long-acting beta 2 agonists, such as salmeterol, may increase the risk of asthma-related death. Therefore, in treating asthma patients physicians should prescribe Advair only for those not adequately controlled otherwise, or if their disease severity warrants initiation of therapy with two maintenance therapies. A SMART trial evaluated the safety of salmeterol or placebo added to usual asthma therapy showed increase in asthma related deaths for patients receiving salmeterol. This totaled 13 patients in the Serevent group out of 13,176 versus 3 in the placebo group out of 13,179. Data from that trial is not adequate to determine if concurrent fluticasone use modifies this risk. Since patients with COPD often have risk factors for reduced bone density, periodic assessment of bone density and periodic eye exams should be considered. Dr. Zarling opined that there would be favorable cost savings for Advair versus individual components. Based on the data and recommendation of the guidelines, Medicaid patients are best served if Advair Diskus is on the PDL without restriction. As for Flovent, Dr. Zarling pointed to the Oregon evidence-based practice center review, and stated that there are three available strengths of Flovent. This provides an effective way to deliver the needed dose with a reasonable number of puffs, as opposed to some products in the inhaled corticosteroid class. A data base analysis done by David Stemple suggested that total health care costs may be lower for patients using Flovent, low-strength prescriptions compared to patients filling prescriptions for other inhaled corticosteroids. Based on this, the Medicaid population would be best served if Flovent were available on the PDL.

Dr. Brodsky asked about the 13 versus 3 asthma related deaths in the two groups mentioned in the SMART trial. Dr. Zarling replied that she wanted to emphasize that this is a small difference when considering the number of patients in each class. She wanted to keep the numbers separate for clarity.

Dr. Demain stated that in the African-American group, which was a little over 1000 patients, there were 8 deaths in that group. This is quite high compared to the Caucasian group. The risk is a 7.6 ratio. Dr. Zarling stated the risk ratio was approximately 4, which is significantly higher than the Caucasian group. Dr. Demain stated that the data was also diluted in this study, if one looks strictly at death rates, and it was alarming. But when blended with severe events, it diluted out.

Dr. Sater gave the First Health presentation for this category. There are six available agents. One agent, fluticasone, is available in combination with salmeterol. All agents are approved for maintenance and prophylactic treatment of asthma. Other indications vary by agent. Two major delivery devices include the dry powder inhaler and metered dose inhaler. Only budesonide and mometasone are available in dry powder inhaler. All have similar efficacy and tolerability when used in equal potent doses. Asmanex and Advair contain lactose in their delivery device. Other warnings, drug reactions and interactions are similar for all agents. In April there were 793 claims with Advair claiming 48% market share. Flovent HFA has 28%, Pulmicort Respules has 12%, QVAR 5%, Pulmicort inhaler 4%, Azmacort 2% and Asmanex and AeroBid have less than 1% each. There is 97.5% compliance in this class. Flovent and QVAR are preferred for all age groups and Pulmicort Respules are approved for children under 12, Advair also is preferred.

In previous discussions, Pulmicort Respules were approved because of the nebulized form. The agents were deemed equally efficacious and class effect was declared. Significant changes since the last review include Asmanex entering the market place. It was reviewed last time, but it was not a significant presence in the market place until the review was over. The Advair label changes have been made since the last review. Dr.

Woodard prefers fluticasone in his practice, due to more available dose options. He also supports Advair, feeling it is safe due to the fixed presence of a inhaled corticosteroid and long-acting beta agonist.

Dr. Demain stated that he thinks Advair is a good product when used appropriately. It is a recommended add-on therapy with long-acting bronchodilator/inhaled steroids. The problem we continue to see in Alaska is reflected by sheer numbers in that it is the most over-prescribed and inappropriately prescribed drug when it is used for mild asthma. Patients are started on this drug before they try anything else, which is in violation of the current guidelines. New guidelines will be coming out this fall. The data over the last decade has supported the FDA documentation. Unfortunately, there is not a mechanism to say use this medication conditionally.

Dr. Brodsky asked if the committee should not prefer it. Dr. Demain said that there is a protocol set up by the guidelines for treatment. Dr. Brodsky stated that he is surprised that people jump into Advair first before trying anything else, which is not appropriate in all cases. Dr. Liljegren stated that her understanding of previous discussions is that this was something for the utilization review committee. She expressed concerns about compliance if there were a prior authorization procedure placed with this medication.

Dr. Carlson stated that the product put into a nebulizer makes pediatric delivery easier, and even for some adult patients. He recommended the committee have at least one nebulizer product available. Dr. Carlson stated that there is a lot of fear of risks in society and in making formulary decisions. The committee is affected by the public's worry about risk. If there are multiple products available and one has more risk, then the committee needs to be careful with that. Advair is one medication that has had risks come up in the past year, and this should be considered.

Dr. Brodsky asked which products are available for nebulizer and Dr. Sater answered it is just Pulmicort Respules now. Dr. Greear asked how Advair fits into the discussion of combination products. Dr. Brodsky stated that the two medications are being discussed today. Dr. Hunt stated this is not the same as the regular combination issue, as this medication may be more hazardous in certain situations. Dr. Briggs stated she would prefer not to see Serevent used without a steroid inhaler.

Dr. Demain stated that the recommendations for the guidelines involves a tiered approach to treatment based on the level of asthma a patient is determined to have. It is not just picking one inhaled steroid, it is picking a low, medium and high potency medication. In the category of low potency, that is beclomethasone, triamcinolone and flunisolide. Budesonide is medium potency with fluticasone and mometasone as the high potency drugs. The other important issue to note is budesonide is the preferred agent during pregnancy and the only one available in nebulized solution for infants and adults with difficulty using inhalers. These unique properties should be considered.

Dr. Demain asked what the current PDL is for this class. Dr. Sater answered that Flovent and QVAR are currently preferred with Pulmicort for people under 12. QVAR is in the low to medium potency, and fluticasone is high potency. Dr. Demain recommended against flunisolide since patients just will not use it. Dr. Sater said that market share for this is 0.12% with 2 claims in April.
Dr. Demain suggested including varying potency levels in the PDL, with competition between each potency level medication. He also suggested budesonide be preferred for nebulized solutions and during pregnancy.

DR. DEMAIN MOVED TO INCLUDE A LOW TO MEDIUM POTENCY MEDICATION (either beclomethasone or budesonide), AND A HIGH POTENCY MEDICATION (fluticasone or mometasone) ON THE PDL WITH BUDESONIDE PREFERRED FOR NEBULIZED SOLUTIONS AND DURING PREGNANCY. MR. MILLER SECONDED.

Dr. Sater pointed out that Respules are not needed for pregnancy. There is pretty low use of Pulmicort inhalers, but Respules have a fair amount of use. Dr. Briggs stated that providers can also write "medically necessary."

DR. DEMAIN ACCEPTED AN AMENDMENT TO INCLUDE BUDESONIDE RESPULES. DR. HUNT SECONDED.

MOTION CARRIED UNANIMOUSLY.

7. Re-review of Short-acting B2 Agonists

There was no public comment for this class.

Dr. Sater gave the First Health presentation on this class of drugs. There are two delivery mechanisms available, inhalers and nebulizer solutions. There are four inhalers available and three nebulized available. All are indicated for treatment of bronchospasm. All are relatively selective for the beta 2 receptors and all agents have similar efficacy and tolerability. In Alaska, there were 1798 claims in April. Albuterol in all forms had 94% market share with 3% in HFA form. Xopenex had 2% market share and AccuNeb had 1%. Maxair, Alupent, Proventil and Ventolin had less than 1%. There is 94% compliance in this class. All forms of generic albuterol are currently preferred. In previous discussions, HFA product was preferred and agents were deemed therapeutically equivalent.

Since the last review, there has been data published about Xopenex or levalbuterol reducing hospital admissions in pediatric patients presenting to the emergency room with bronchospasm or asthma-related diagnoses. Dr. Woodard feels most patients can be appropriately managed with albuterol HFA and recommended this alone be added to the PDL. He tries to move all patients toward inhalers and away from nebulized products.

Dr. Demain stated that one thing to be sure of is to use ampules rather than multidose solution, which has a chemical shown to induce asthma. This should be used only in unit dose ampules that are preservative free. Dr. Sater stated that albuterol for nebulization solution comes in concentrated multidose vial or in single dose.

Dr. Liljegren suggested that if AccuNeb is included that there be some dosage restrictions on it. This is due to albuterol not always being available. This may not be an issue in the future, according to committee discussion. Dr. Demain stated that there needs to be a nebulized albuterol solution, but it needs to be in the unit dose. Albuterol is still the standard in the industry.

Dr. Demain suggested considering this a class effect. Dr. Brodsky suggested we prefer albuterol in all forms, except for multi-dose vials. Dr. Briggs stated it might be worthwhile to put this information and the committee's recommendations on the web site.

DR. DEMAIN MOVED TO PREFER ALBUTEROL IN ALL FORMS EXCEPT FOR THE MULTIDOSE VIAL. THERE WILL BE A NEBULIZED SOLUTION AND AN INHALER.

Dr. Liljegren suggested including AccuNeb also. Dr. Sater reports that there were 18 claims out of 1800 in April. Dr. Brodsky stated that providers can use "medically necessary."

MOTION CARRIED UNANIMOUSLY.

8. Re-review of Long-acting B2 Agonists

Meredith Zarling, PharmD, GSK: Testified about Serevent. The NIH guidelines recommended patients with mild or persistent asthma be on inhaled corticosteroids. If patients are still having problems, then the recommended treatment is a long-acting beta agonist. Alternative therapies are increasing ICS dose to medium dose range. The SMART trial was for Serevent, salmeterol not Advair. The NIH issued evidence-based asthma guidelines clearly recommended the addition of long-acting beta agonist to a corticosteroid as preferred therapy for moderate to severe asthma. The gold guidelines for COPD recommend long-acting bronchodilator therapy in patients with moderate to severe stage COPD. Regular treatment with long-acting bronchodilators is more effective and convenient than treatment with short-acting beta agonists and improves health status. The label change/box warning recommends starting with low to medium dose inhaled corticosteroid unless it is felt the patient warrants dual controller therapy. She asked that Serevent remain available to Medicaid patients in Alaska in an unrestricted basis.

Dr. Sater gave the First Health presentation on this class of medications. There are two available agents: salmeterol, which is also available in combination with fluticasone. Formoterol will likely be available soon in combination with budesonide. Both agents are indicated for maintenance treatment of asthma, exercise-induced bronchospasm and maintenance treatment of bronchoconstriction and bronchospasm in patients with COPD. Formoterol has more rapid onset of action; however, neither agent should be used as a rescue medication. Tolerability and efficacy are equivalent between the agents. In Alaska in April there were only 22 claims for these drugs. Serevent has a 59% market share, and Foradil has 41%. Serevent is currently preferred, giving a 59% compliance rate in this class. Previous discussions centered around the SMART trial. The agents were deemed equivalent and there has been significant decline in the use of long-acting beta agonists. At the time of the last review, there were about 100 claims per month. Significant changes since the last review include the November 2005 FDA warning about long-acting beta agonists. Dr. Woodard has no preference for either agent and sees limited utility for either drug alone.

Dr. Demain asked about African-American populations with 8 deaths using salmeterol compared to 1 in the control group. This is a substantially increased risk. Long-acting bronchodilators have been shown to potentially increase the risk of bad outcome, as well as increase airway hyperreactivity and decrease response to rescue edications. Studies have revealed that in patients with Arg-Arg 16 codon, their risk of worsening with a long-acting bronchodilator is increased. This is probably about 20% of the population. There is not a way to identify these patients at present. He feels that the risk associated with these drugs is highest when used alone and not in conjunction with an inhaled steroid. That, along with the limited use seen, leads him to recommend these drugs not be preferred and not put on the formulary. If a patient needs it, someone should seriously consider it further. Dr. Briggs stated that she does not think they should be used.

DR. DEMAIN MOVED THAT THESE AGENTS NOT BE PREFERRED. DR. BRIGGS SECONDED.

Dr. Briggs suggested placing a link on the web site to information about this medication, and Dr. Demain recommended a link to the FDA information page.

Dr. Carlson thought the motion addressed the risks very well. He suggested looking at the whole asthma category once the new NIH guidelines come out in the fall. Mr. Miller asked if the committee has the responsibility to require preauthorization. Dr. Sater reported that if there is a prior authorization on this class, the committee can still benefit from having a preferred agent. If there is no preferred agent, there is no additional benefit.

Dr. Conright asked if the committee can say these medications are equivalent, but require prior authorization. They can go out for bidding, but they will be restricted. Dr. Sater answered that they would be restricted and require preauthorization, but there would be a preferred agent with the supplemental rebate. This allows for double checking that patients are also on inhaled steroids if they are prescribed a short-acting B2 agonist. There were 22 prescriptions for this class in April.

Dr. Brodsky restated the motion. Dr. Demain stated he did not want to create barriers or make it more difficult for pharmacists, either. Prior authorization responsibility is on the physician's side, and not on pharmacist's. There is no guarantee, however, that physicians have been educated and therefore pharmacists may have to monitor it anyway. Dr. Hunt stated that he prefers a shift in the responsibility to the DUR, so they can handle any preauthorization declarations.

Dr. Brodsky restated the motion again. Dr. Brodsky stated his preference to have nothing preferred and let DUR send letters to people who write for this medication. Dr. Conright asked about influencing prescriber habits and how far the committee wants to go to do that. Mr. Campana said that the prior authorization would be more influential in changing habits than the DUR process. DUR could review the profiles for these drugs and make other recommendations later on. There could still be an advantage and a chance for education to the prescribing community. Dr. Brodsky asked if there is a prior authorization requirement, would the committee have to do this to Advair Diskus since same drug in that class is included within that medication. Dr. Sater said the committee can decide that individually.

Dr. Brodsky asked if the committee wanted to vote on the previous motion. Dr. Conright stated it is worth discussing if the committee really wants to influence prescriber habits by doing this. This has not been discussed before.

Dr. Demain decided to change his motion. The long-acting bronchodilator is a preferred agent to be used in combination with inhaled steroid in moderate to severe asthmatics. There have been a lot of reports that modified the 1997 recommendations, which will be formally modified this fall. Even with modifications, there is a role for a long-acting bronchodilator. There is no role for it alone, however. With a prior authorization, there is a way to control this somewhat, as the committee has a responsibility to the safety of the population.

DR. DEMAIN MOVED TO CONSIDER CLASS EFFECT WITH PREAUTHORIZATION REQUIRED. MS. STABLES SECONDED.

Dr. Carlson suggested a DUE between now and this fall to be less onerous to practitioners, then the committee can review their position in the fall. If further barriers are needed then, a prior authorization can be placed. There are many different ways to do this, but not one proper way.

MOTION CARRIED UNANIMOUSLY.

Dr. Brodsky reviewed that the committee had made a prior decision about combination agents. If both agents were preferred, and it was cost neutral or beneficial, then they would appear on the PDL as preferred agents. There is a possibility of that now with Advair Diskus since a relative class effect was declared. Based on that discussion, the committee needs to discuss Advair and decide how to approach it.

Dr. Demain stated that the reason for prior authorization on the long-acting B2 Agonists was to minimize that being used as monotherapy, so he does not think that applies here. Dr. Hunt stated that Advair's use in mild, ntermittent is problematic. Dr. Briggs stated that patients are not classified at all, or are classified incorrectly. Dr. Hunt stated that a prior authorization process could drive a provider to classify this. It would be awkward and he would resent it himself. Dr. Hunt reiterated Dr. Conright's point about the committee's role in educating providers.

Dr. Sater suggested it could be set up like the PA process. Dr. Brodsky stated this would require documentation of patients being on a steroid inhaler. Dr. Briggs stated there are patients who have been on Advair for a long time and this would go into effect. Dr. Conright said they could be grandfathered in. Dr. Sater agreed, stating this would be impacting prescriber habits going forward with no way to go back more than 12 months, except with a DUR review.

DR. GREEAR MOVED TO HAVE ADVAIR CONSIDERED IN ITS OWN CLASS AND BE A PREFERRED AGENT. DR. MACIEJEWSKI SECONDED.

Dr. Demain asked if the committee could say instead that we will put this in its own class and consider it a class effect, since there will be other drugs in this class. Dr. Brodsky stated that there are no other drugs in the class right now. There was some discussion about tabling the discussion. The first available DUR meeting would be September 15, 2006.

MOTION PASSED WITH THREE OPPOSED.

Dr. Hunt asked if the committee could hear a report from DUR routinely. Mr. Campana stated he could produce a different report for that.

THE COMMITTEE AGREED UNANIMOUSLY TO RE-REVIEW ASTHMA MEDICATIONS WHEN THE NEW GUIDELINES ARE PUBLISHED THIS FALL.

9. Re-review of Antifungals

Andrew Shim, PharmD, Novartis: Testified via telephone about Lamisil. It is indicated for treatment of onychomycosis. It is currently on the PDL and has been since the PDL's inception. The data shows clinical superiority and advantage of Lamisil to other agents not on the PDL. The British Journal of Dermatology Guidelines in 2003 showed Lamisil as first line treatment. Studies demonstrate higher cure rates and superior mycological cure rates compared to Sporanox. Lamisil is therapeutically superior. The LION study evaluated efficacy and safety of Lamisil versus Sporanox and showed a better cure rate with Lamisil. The study was also conducted as part of a long-term five year efficacy evaluation. Lamisil was shown to have significantly more patients remaining mycologically cured at the end of 54 month followup without needing second intervention

treatment. Lamisil has no clinical drug interactions or episodes of hypoglycemia in patients taking diabetic medications. Lamisil does not have warnings, like Sporanox.

Dr. Sater gave the First Health presentation on this class. There are three available agents. Griseofulvin is fungistatic and the others are fungicidal. Different formulations of griseofulvin alter the GI absorption of that drug. It has a less attractive and unique adverse drug reaction profile. Adverse drug reactions of Lamisil and Sporanox are similar. Drug interaction profile was extensive with Sporanox but significant with Lamisil and griseofulvin also. There were 60 claims for drugs in this class in April. Lamisil has 58% market share and Grifulvin B has 18%. Sporanox has 7% and Gris-PEG has 5%. Lamisil is preferred and Grifulvin B preferred for pediatric patients. There is 76% compliance in this class. Previous discussions were dominated by the issue of having these agents on the PDL at all. There have been no significant changes since the last review. Dr. Burton Janis does not treat onychomycosis in his practice. Dr. Brownsberger feels Lamisil has fewer toxicities, and he prefers this.

Dr. Demain stated that in pediatrics, they treat a fair amount of tinea capitis, corporus and cruris. Tinea capitis has limited therapies and griseofulvin is the drug of choice. It comes in suspension and tablets. He asked that this be considered for separate reasons, not just for onychomycosis. Dr. Liljegren stated she was one of the participants troubled by this drug class being preferred. She believes this class may be served by going to review and getting prior authorization. There is a difference between treating a child with tinea capitis and treating a patient with onychomycosis on one toenail with no other risk factors. The indication needs to be looked at and authorized. Dr. Hunt stated he agrees with Dr. Liljegren, as did Dr. Briggs.

Dr. Carlson asked if anyone knew the incidence of liver failure with these drugs. Dr. Hunt stated he has not seen this, but he does not use it much. Dr. Hunt stated he worries about QT issues and multiple interactions. Dr. Briggs said her reference is 1 to 10%. Dr. Brodsky stated that by not preferring it, providers can write "medically necessary" and then we lose money. It does not change behavior either.

Dr. Sater reported that dual eligible patients have not had a significant impact. In December 2005, there were 93 claims, as opposed to 60 claims in April. Dr. Hunt stated that he is willing to do what the committee did last year.

Dr. Liljegren asked if DUR could consider prior authorization of this medication also. Dr. Brodsky answered that the committee could do both: refer to DUR and require prior authorization. Dr. Conright asked how often the DUR chooses prior authorization. Mr. Campana stated this usually comes from the DUR recommendations. This committee is theoretically part of DUR, so it can issue prior authorization requirements. All DUR committee members serve on this committee also. It is possible to make a recommendation and the State will do its best to carry it out.

Dr. Demain asked if the 60 prescriptions were using pulse therapy or continuous therapy. Studies show pulse therapy is just as effective and uses half the amount of drug. Dr. Sater did not have that information available. Dr. Conright stated that DUR may want to use prior authorization, as this is largely a cosmetic issue. She states that 90% of her patients have it. Dr. Boothe stated that most patients on this medication were diabetic, according to her recollection of DUR discussions.

Dr. Liljegren presented the scenario of a Medicaid patient coming in asking for this medication. She states that she would have a hard time saying no unless there was a prior authorization or criteria. This makes her

treatment different for that person than another patient and makes her decision not to treat based on cost. She does not feel she could do that.

Dr. Demain stated that some patients still need prior authorization from insurance companies. Dr. Liljegren stated that some people choose to pay on their own. Medicaid patients do not have this option. Dr. Brodsky pointed out not withholding medication based on cost, but instead on side effect protocol, risk, and this being a cosmetic issue.

Dr. Boothe stated that the committee has not discussed the utility of these medications for pediatric indications. There seem to be two different issues. Dr. Demain pointed out that there is consideration for diabetics and pediatric patients to include in this discussion also. Dr. Briggs stated that griseofulvin has indications for children, but beyond that, she does not know what else to discuss.

DR. CARLSON MOVED TO HAVE A GRISEOFULVIN PRODUCT (INCLUDING ONE IN SUSPENSION FORM) ON THE FORMULARY AND LAMISIL WITHOUT RESPECT TO AGE. DR. DEMAIN SECONDED.

Dr. Demain suggested placing a stipulation to limit use in high-risk patients such as diabetics. It will not be a restriction but will raise awareness. Dr. Liljegren asked if the discussion was for preferring griseofulvin for pediatrics and not for everyone. Dr. Brodsky confirmed this. The committee decided to leave the motion intact as above. The motion would widen the preferred from the previous decision by the committee.

MOTION PASSED WITH ONE OPPOSED.

OFF THE RECORD AT 9:48AM
ON THE RECORD AT 10:10 AM

10. Re-Review of Antivirals

Andrew Shim, PharmD, Novartis: Testified via telephone about Famvir, an oral antiviral agent currently on the PDL since the inception of the PDL. Famvir is FDA-approved for acute herpes zoster or shingles, and for treatment or suppression of genital herpes, including recurrent herpes in HIV-positive patients. The new development is in the fall of 2005, a supplement was filed for single day treatment of recurrent genital herpes and for single dose therapy for cold sores. Famvir is the only antiviral proven to shorten duration of postherpetic neuralgia. It shortens the duration by 100 days versus placebo. Regarding suppression, Famvir can suppress for up to one year, or 290 days more herpes free versus placebo.

Dr. Sater gave the First Health presentation on herpes antivirals. There are three available agents, which are all FDA indicated for treatment of genital herpes infections, acute and suppressive. FDA indications vary, but clinically they are all used for most indications. Acyclovir is available in a number of dosage forms. Efficacy, adverse drug reaction profiles, and drug interactions are similar for all agents. There were 238 claims in Alaska for drugs in this class. Acyclovir has 55% market share, Zovirax brand has 16%, Valtrex has 36% and Famvir 8%. Generic acyclovir, Valtrex and Famvir are currently preferred. There is 84% compliance in this class. There was no discussion last year and there have been no significant changes in this class. Both Dr. Janis and Dr. Brownsberger feel there is a role for acyclovir in the treatment of herpes infections. Neither felt there was a clinically significant difference between Famvir and Valtrex, but they recommended at least one agent be

included on the PDL: Famvir or Valtrex and acyclovir. They stated this preference mostly for zoster due to tolerability.

Dr. Demain asked if previous decision was for class effect, which Dr. Sater confirmed.

DR. BERGSON MOVED TO CONSIDER CLASS EFFECT AND INCLUDE ONE ORAL AGENT. DR. DEMAIN SECONDED.

Dr. Briggs asked about the use of creams in this class, and Dr. Sater answered that there is very little use of them currently. Dr. Stransky stated that there clinical significance has not been shown for effectiveness of the creams. STD guidelines recommended the creams not be used.

MOTION CARRIED UNANIMOUSLY.

11. Re-review Oral Antibiotics

A. Second generation cephalosporins:

Dr. Sater gave the First Health presentation on this class: There are four available agents in this class. Second generation cephalosporins show less gram positive coverage but extended gram negative coverage compared to first generation cephalosporins. Three of the agents are available in generic form. Eleven major FDA approved indications for drugs in this class exist. These agents can be considered therapeutically equivalent for many community acquired infections. Adverse drug reaction profiles, contraindications, drug interactions and warnings are similar in most agents. The adverse drug reaction of cefaclor is poorer than the others. In April in Alaska, there were 73 claims. Ceftin suspension has 37% market share, cefuroxime has 30%, Cefzil suspension has 14%, Cefzil and cefaclor have 8% and Lorabid suspension has 3%. Currently cefuroxime in all forms and Cefzil are preferred. There is 89% compliance in this class.

Previous discussions included lengthy discussion of adverse drug reactions with cefaclor and taste problems with suspensions. Cefzil and Ceftin were considered equivalent and Cefzil suspension was preferentially preferred. There have been no significant changes since the last review. Dr. Janus prefers cefuroxime in treating anaerobes, staph and strep infections. Dr. Brownsberger feels they are all equivalent but cefuroxime is on the Providence formulary.

Dr. Demain stated that Cefzil was discussed due to taste, which he feels should still be a consideration. The committee discussed the taste of various medications and whether to declare class effect.

DR. BERGESON MOVED TO DECLARE CLASS EFFECT, BUT NOT INCLUDE CEFACLOR. CEFZIL SUSPENSION WILL BE INCLUDED. DR. DEMAIN SECONDED.

MOTION PASSED UNANIMOUSLY.

B. Third generation cephalosporins

LouAnn Rondorf-Klym, PhD, Abbott: Testified about Omnicef. She spoke about the spectrum of activity or compliance and the safety issues. Omnicef in the pediatrics realm is indicated for acute otitis media, tonsillitis, pharyngitis and complicated skin infections. For adults, it is indicated for acute maxillary sinusitis, community acquired pneumonia and acute exacerbation of chronic bronchitis. It has the gram positive coverage characteristics of second generation cephalosporins and additional coverage of third generations for gram negative activity. Compared to other antibiotics such as Vantin or Ceftin, Omnicef is superior against gram positive organisms, like strep pneumo related to AOM or sinusitis. It is indicated for AOM for five day treatment which can provide some cost savings and every day dosing for sinusitis. In five head-to-head studies of pediatric populations for palatability, it rates higher than Ceftin, Augmenting, Cefzil and Zithromax. The Stanford Guide, Pocketbook Guide, Harriet Layne handbook, Nelson's and American Academy of Sinusitis recommended Omnicef for AOM and sinusitis treatment. It is a second or third line treatment.

Dr. Sater presented information on the five available agents for this class. Indications and antimicrobial coverage vary by agent. Therapeutic efficacy is somewhat equivalent between agents. The adverse drug reaction profiles, drug interactions, warnings and contraindications are similar. In April, there were 430 claims. Omnicef suspension has 79% market share. Omnicef tablets have 15%. Vantin and Suprax has approximately 2% each. Spectracef has less than 0.5% market share. Omnicef and Suprax suspension are preferred. There is 96% compliance in this class. In previous discussions, agents were deemed therapeutically equivalent. Omnicef suspension was preferentially preferred due to taste. There have been no significant changes since the last review. Dr. Janis does not use these drugs in his practice. Dr. Brownsberger seldom uses them and feels the necessity of using any drugs in this class is questionable.

Dr. Brodsky pointed out that only Vantin and Suprax are indicated for treatment of gonorrhea. He recommended one of them be available. Dr. Bergeson stated in pediatrics they use Omnicef as a second or third agent. It has good taste. Suprax is good for UTIs in children. Vantin suspension does not taste very well and is not accepted by any kid he knows of. Dr. Hunt asked why one uses more Suprax in UTIs, and Dr. Bergeson answered it was mostly due to taste.

Dr. Brodsky referred to the new otitis media guidelines talking about treatment without antibiotics first. If that is not successful, amoxicillin is used first. If this is not successful, other amoxicillins are used before 3rd generation cephalosporins. Dr. Brodsky is surprised then that this class is used as much as it is. Dr. Sater stated there were almost 2000 claims for amoxicillin or penicillins.

DR. BERGESON MOVED TO KEEP THE RECOMMENDATIONS THE SAME AS LAST YEAR. AGENTS WERE DEEMED THERAPEUTICALLY EQUIVALENT, BUT OMNICEF SUSPENSION WAS INCLUDED. DR. HUNT SECONDED.

MOTION PASSED UNANIMOUSLY.

C. Second generation quinolones:

Dr. Sater presented information on the four available agents in this class. All are effective for UTI. Other indications vary by agent. Ciprofloxacin is the only one available in suspension. The adverse drug reaction profiles, drug interactions, warnings and contraindications are similar for drugs in this class. In April, there were 151 claims for this class. Ciprofloxacin has 92% market share, Cipro suspension has

3%, Cipro XR has 3%, Noroxin, ofloxacin and Cipro each have one claim. Generic ciprofloxacin is the preferred agent and there is 92% compliance in this class. Previous discussions addressed treatment of STD with quinolones. Development of pseudomonas resistance was also discussed. Class effect was declared but ciprofloxacin was preferentially preferred. There have not been any significant changes. Dr. Janis and Dr. Brownsberger feel ciprofloxacin is the superior agent in this class primarily due to pseudomonal coverage.

Dr. Liljegren stated that she did not think Noroxin should be preferred, as she does not feel it has anything to make it stand out in this group.

DR. CARLSON MOVED TO ADOPT LAST YEAR'S PREFERRED LIST, DECLARING A CLASS EFFECT BUT PREFERENTIALLY PREFERRING CIPRO. DR. DEMAIN SECONDED.

MOTION PASSED UNANIMOUSLY.

D. Third generation quinolones:

Fred Meister, PharmD, Schering Plough: Testified about Avelox, a broad-spectrum bacteriocidal that demonstrates clinical efficacy in treatment of aerobic and anaerobic, gram positive and gram negative organisms including multi-drug resistance strains. It has demonstrated clinical efficacy against infections with mixed aerobic and anaerobic infections and single etiologies. FDA approved indications is for adults 18 years of age or older. It is approved for acute bacterial sinusitis, acute bacterial exacerbation for chronic bronchitis, community acquired pneumonia, uncomplicated and complicated skin infections. The most recent FDA approval is for intraabdominal infections. It is the only fluoroquinolone with that indication along with one other. The pharmacokinetics have not changed in the last year. There is no need for dose adjustment based on gender, race or age. It has a dual mechanism of action. There has been a Capri study looking at the use of Avelox versus levofloxacin in elderly patients with community acquired pneumonia. Drugs were equivalent in efficacy, but Avelox had a more rapid onset of symptom relief and resolution than levofloxacin. This is a cardiac safety study by the FDA that found no difference with the two drugs in regard to cardiac safety. When compared to standard antibiotic therapy in acute bronchitis exacerbation, there was almost equivalent activity in outcome. The interval between events was increased also. Other studies show reduction in recurrence of acute sinusitis and equal occurrence of diarrhea.

Alena Jandourek, MD, Pricara/Ortho McNeil: Testified about Levaquin. It has outstanding efficacy in the treatment of respiratory tract infections, skin infections, urinary infections and pneumonia. It has been most extensively studied in patients with community acquired pneumonias. It has demonstrated excellent efficacy. Success rates are 97% in severe community acquired pneumonia and 100% in bacteremic community acquired pneumonia and 100% in patients with penicillin resistant strep pneumoniae and 97% of patients over age 65. It has over 320 million prescriptions worldwide. Newer agents have lower usage and safety profiles do not have the same good track record. There has been no increased report in dysglycemia events in levofloxacin over its history to date. QT prolongations have not been reported. Levofloxacin has maintained its susceptibility since its introduction. There has been no strep pneumoniae resistance reported to levofloxacin from 2002 to 2004. In contrast, penicillin resistance in Alaska is 24% for the same time. Levofloxacin was recently approved for a five-day course for community acquired pneumonia in the 750 mg dosage. In the clinical trial, patients treated with five

days of levofloxacin had a one day shorter duration of fever compared to those treated with 10 days. The Capri study that compared moxifloxacin to levofloxacin were both for 10 days. Shorter courses of treatment are recommended by the World Health Organization. The benefits are potentially of shorter exposure to antibiotics causing less resistance and potential for more patient compliance. Since levofloxacin is on most hospital formularies, transition from inpatient to outpatient settings mean less chance of inappropriate use of these medications.

Dr. Carlson asked why the VA chose Tequin. Dr. Jandourek stated she believed this was due to cost. It is no longer on their formulary, however, at least not in the Lower 48.

Dr. Sater then presented information about the four available agents. These have effectively been reduced to three agents, since Tequin was withdrawn from the market. FDA approved the medications for a variety of indications. There is no clinical evidence to suggest superiority of one agent over another for respiratory infections. Factive is associated with severe rash and is not widely used. All agents are dosed daily. In April, Alaska had 184 claims for this class. Levaquin has 96% market share. Avelox has 3% and Tequin has 1%. Levaquin is the preferred agent and there is 96% compliance in this class. Previous discussions included QT prolongations with Tequin and the motion was made to exclude Tequin from the PDL. Levaquin was preferentially preferred with much support from local physicians. Significant changes since the last review include the removal of Tequin from the market place. Both Dr. Janis and Dr. Brownsberger prefer Levofloxacin to others in this class, but pseudomonal coverage is poor.

DR. HUNT MOVED TO DO THE SAME AS LAST YEAR, PREFERRING LEVAQUIN. DR. DEMAIN SECONDED.

Dr. Brodsky asked about the American Thoracic Society guidelines for community acquired pneumonia treatment. Dr. Carlson stated he believes it is treatment with cephalosporin then azithromycin. Dr. Sater stated that azithromycin is also a five-day treatment, not just levofloxacin.

MOTION PASSED UNANIMOUSLY.

E. Macrolides:

LouAnn Rondorf-Klym, PhD, Abbott: Testified about Biaxin XL. For pediatric patients, Biaxin is indicated for acute otitis medial, pharyngitis, sinusitis, pneumonia and uncomplicated skin infections. For adults, it is indicated for bronchitis and has significant survival benefit for HIV patients for prophylaxis and/or treatment. It is the only advanced generation macrolide indicated for H. pylori and in that treatment it can decrease recurrence of ulcers. As for safety and adherence, it is recommended without warning or restrictions for patients in transition from IV to oral antibiotics for pneumonia. Biaxin has an excellent safety profile over a decade of use and over 100 countries. It has been studied in the US in over 6000 patients in nine disease states. Biaxin XL has proven efficacy and safety as noted in multiple guideline recommendations. They are studying the immunomodulatory effects of Biaxin and asthma clinic research network is doing that.

Dr. Stransky asked about the half life. Dr. Klym stated it is about four to five hours.

Dr. Sater presented information about the three available agents in this class. Azithromycin is available in many dosage forms. Indications vary among the agents. Erythromycin is not well tolerated due to GI adverse drug reactions. Azithromycin and clarithromycin are dosed fewer times daily and have fewer adverse drug reactions. There is similar efficacy between those two agents. Newer agents show better tissue penetration in clinical studies. In April there were 1315 claims for macrolides in Alaska. Generic azithromycin has a 45% market share, Zithromax suspension has 42%, Zithromax tablets have 4%, and Biaxin XL has 2%. Biaxin tablets has 1%, Biaxin suspension has less than 1% and all erythromycin products combined have a 5% market share. All forms of Biaxin and Zithromax are preferred, along with various erythromycin salts and generic azithromycin. There is 96% compliance in this class. In previous discussions, there was a significant discussion of Ketek, which is not included in this class. Class effect was declared and generic azithromycin was preferentially preferred. Dr. Janis prefers azithromycin because it has good antimicrobial coverage, few side effects and cleaner drug interaction profile. It is also easier to dose. Dr. Brownsberger feels there are distinct roles for azithromycin and clarithromycin. He recommended both be added to the PDL.

Dr. Liljegren asked if suspension forms need to be required or not. Dr. Sater stated that would be best. Dr. Bergeson had a big article about Ketac, which is not in this class. Dr. Sater mentioned that there was discussion last year about concern over appropriate use of Ketac. Average use in Alaska is 15 to 20 claims per month.

Dr. Brodsky asked if all erythromycins were on the formulary, and Dr. Sater confirmed that these were declared class effect. Not every single erythromycin is preferred, however. Dr. Demain agrees with Dr. Brownsberger that there are more problems with Pertussis, for which azithromycin is not effective. Dr. Hunt asked about the differential activity for Pertussis. Dr. Carlson stated that the value of antibiotics with Pertussis is debated.

Dr. Stransky asked the committee for their recommendation for serious acute infections, do they avoid azithromycin since it does not act quickly enough. Dr. Brodsky stated he did not think so. Dr. Hunt clarified that clarithromycin made it to the formulary because it came in cheaper than generic azithromycin. Dr. Sater said it was not necessarily cheaper. The committee declared a class effect, but generic azithromycin was preferentially preferred. Dr. Brodsky pointed out that clarithromycin had little use.

DR. HUNT MOVED TO DECLARE MACROLIDES EQUALLY EFFICACIOUS, BUT PREFER AN AZITHROMYCIN PREPARATION. DR. BERGESON SECONDED.

MOTION PASSED UNANIMOUSLY.

12. Re-review Hepatitis C Drugs

Steve Ischista, PharmD: Testified on behalf of PEG-Intron. It is one of two drugs currently indicated for treatment of hepatitis C. He reviewed the evidence-based outcome trials since his appearance before the committee last year. All studies are randomized trials. He also commented on comparative trials currently underway. A community based trial looked at a dosing of ribavirin from 800 to 1400 mg given daily with a standard weight-based dosing of PEG-Intron. The efficacy of the weight-based dosing was superior to the ribavirin. The new concept of rapid viral response is a reduction in the viral load at the end of four weeks. Using

this for a subset of genotypes 2 and 3, which is very prevalent in the Native Alaskan community, there is evidence that the treatment can be reduced from 24 to 12 weeks. Using the rapid viral response data, genotype 1 patients with low viral load can shorten treatment from 48 to 24 weeks with equal efficacy. The comparative trials consist of one done by Valiant. This was powered to show efficacy of their drug to ribavirin. They presented data recently in Vienna. Prior to that, they introduced their data on a dose ranging study. This was done with Pegasys. Because the data for the sustained viral response, which is a cure defined as virus free for six months at the end of treatment. The results of the two trials are not comparable until the Visor 2 phase 3 data is disclosed. This is anticipated in November. The other trial involves 3000 patients powered to show efficacy of one pegylated interferon over the other. There will be two arms to this study. This is a comparison of treatment regimens with different ribavirin doses. Data for that is not available yet but is expected for next year. Therefore, he asked that both drugs have equal access.

Mark Loveless, MD, Roche: Testified about Pegasys. It is a unique pegylated interferon and it is the FDA approved drug for three indications: hepatitis B, coinfection with hepatitis C, and HIV and for monoinfected patients with hepatitis C. Roche has performed eight large randomized prospective trials with results in six New England Journal articles. Hepatitis B is a problem, especially on the Pacific Rim. Pegasys has shown it is better than ranitidine in attaining a response to hepatitis B with 40% response compared to 30% with ranitidine. In hepatitis E positive patients, we can get an E antigen seroconversion but also a hepatitis B surface antigen conversion in about 9% of patients, which does not happen with oral agents. Two out of every five patients coinfected with HIV and hepatitis C can be cured of their hepatitis C. In monoinfected patients, NEJM reports that Pegasys produced a sustained viral response across the board in 56% of patients as opposed to pegylated alfa-2b which was 46%. When looking at genotype 1 patients, 43% of patients have sustained viral response. With genotype 2 and 3, which are easier to treat, the range is 84% with 24 weeks of therapy. The real issue is that in a study presented for the first time in Europe very recently, there is now data from a large trial that 24 weeks of therapy is the best for genotype 2 and 3 patients. Sixteen weeks did not perform as well. Pegasys has demonstrated efficacy and safety. It is easy to use and is a single dose. It requires no mixing which improve and help compliance. He asked the committee not to change the preferred status of Pegasys.

Dr. Sater gave the First Health presentation on this class of medications. There are currently two agents available with similar adverse drug reaction profiles, drug interactions, warnings and contraindications. Published head-to-head trials are lacking but underway and sustained virological response rates appear to be similar with both agents. In Alaska in April there were two claims, one for each drug. In previous discussion, the difficult nature of treating hepatitis C was discussed and a class effect was declared. There were not a lot of significant changes, but by the next review, there will probably be more published trials. Dr. Sahagun prefers PEG-Intron in his patients, as he can use a weight-based dosing regimen and get more drug into a patient, but he uses both. Pegasys is the current preferred agent. Last time, the committee declared a class effect.

DR. STRANSKY MOVED TO DECLARE CLASS EFFECT. DR. HUNT SECONDED.

MOTION CARRIED UNANIMOUSLY.

Dr. Brodsky reminded the group that there is a working lunch session after this meeting.

13. Re-Review of Ribavirin

There was no public comment for this class.

Dr. Sater gave the First Health Presentation for this class. There are two branded and one generic ribavirin products, tablets capsule and solution. The adverse drug reaction profiles, drug interactions, warnings and contraindications are similar for both agents. There were four claims for ribavirin in Alaska with three generic products, Copegus had one claim. Copegus and ribavirin generic are preferred. Previous discussion was not lengthy and class effect was declared. There have been no significant changes. Dr. Sahagun did not have a preference for any brand in this class. He stated that use of generic ribavirin was acceptable.

DR. DEMAIN MOVED TO CONSIDER THIS A CLASS EFFECT. MR. MILLER SECONDED.

MOTION PASSED UNANIMOUSLY.

14. Final Comments by Chair or other members

Dr. Brodsky asked that people respond to their request for reappointment by those whose terms are up. Mr. Campana reminded members that if they did not receive a letter, it is because their terms are not nearing the end.

Mr. Campana gave a report about the mental health drugs. Prior to addressing these, there must be a prior authorization out for morphine, as this included opioids with mental health drugs. Prior authorization will be placed on morphine to bring it to parity with OxyContin and Duragesic. Rather than move forward with implementation of mental health drugs, we will re-review them in October.

Dr. Hunt asked if the mental health drugs included mood stabilizers and antidepressants specifically. Mr. Campana confirmed that it excludes antipsychotics. It does include hypnotic, SRI, SSRIs, stimulant, and antidepressant medications.

The minutes from the April 21, 2006 meeting were reviewed. The following corrections are noted:

- Page 7 should say Dr. Sater stated that people do not tolerate these drugs, especially if they are not *titrated*
- Page 9 should say Dr. Conright stated that with the population she treats she *almost* always uses
- glipizide.
- Page 14 should say Dr. Liljegren asked *about* macular edema.

Minutes were approved as amended.

Dr. Brodsky read the dates and times of the next meetings, tentatively. The committee meets generally on the 3rd Friday of each month but this will be the last meeting for the spring.

Mr. Campana thanked the members of the committee for their service.

MEETING ADJOURNED AT 11:25 AM.